

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Applicant thanks the Examiner and his supervisor for the helpful interview on May 11, 2007.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 2-5 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 15 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

The Examiner indicated that the phrase “strand or seed formed of a synthetic polymer, an inorganic material, a natural material or a shape memory material” in claims 2-5 was unclear since it was not clear whether the inorganic material, natural material or shape memory material was present in component (a) or (b) or in an additional component. In response, claims 2-5 have been amended to specify that the carrier, *i.e.* component (b), is formed of the material specified in the dependent claim. Support for these amendments can be found in the specification at least at page 9, lines 10-11; page 10, lines 18-19; page 10, lines 1 and 10-16; and in claims 2-5 as originally filed. Therefore claims 2-5, as amended, are definite.

With respect to claim 15, the Examiner indicated that the phrase “synthetic hemoglobin-like substances” was unclear. Although Applicant believes that this phrase is clear to one of ordinary skill in the art as referring to substances that increase oxygen perfusion in tissue (as described in the specification in the paragraph bridging pages 16-17), claim 15 has been amended to delete this term. Therefore claim 15 is definite.

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Rejection Under 35 U.S.C. § 102

Claims 1-14, 16-20, and 22-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2001/004567 to Zamora *et al.* (“Zamora”). Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

Zamora

Zamora discloses a bioabsorbable brachytherapy device. Contrary to the Examiner’s assertion at page 4, section 2 of the Office Action, Zamora’s reference to poly(hydroxybutyrate) (*see* Zamora, page 4, para. 0049) does not amount to a disclosure of an elastic strand or seed. As shown by the enclosed document, poly(hydroxybutyrate) is generally characterized as a “brittle” polymer with “low deformability”. (*see* printout from www.ics.frieste/Documents/Downloads/af1665.pdf)

Further, the independent claims, claims 1, 24 and 25 have been amended to specify that the strand or seed contains polymeric setae or anchoring structures. Support for this amendment can be found in the specification at least at page 35, lines 7-10 and 37, lines 19-21. As noted in the specification, the setae or anchoring structures prevent migration of the seed or strand following implantation. In contrast, Zamora does not disclose including any structures in its seeds to prevent migration of the seeds following implantation. Therefore, independent claims 1, 24 and 25, and their dependent claims, claims 2-14, 16-20, 22, 23, and 26, 27, and 29-35, are novel over Zamora.

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Rejection Under 35 U.S.C. § 103

Claim 15 was rejected under 35 U.S.C. § 103(a) as being obvious over Zamora, in view of U.S. Patent No. 4,247,406 to Widder *et al.* (“Widder”). Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

Zamora

As noted above, Zamora does not disclose the claimed elastic seeds or strands which include setae or anchoring structures. With respect to preventing migration of the devices following implantation, Zamora notes that the density of the device is selected to be approximately the same as the density of normal and cancerous tissues (page 7, para. 0083). Zamora explains that by selecting devices with densities approximately equivalent to the density of the tissue in which the devices are placed, “movement of the devices [...] within the body is minimized.” (*Id.*)

Widder

Widder discloses polymeric microspheres containing magnetic particles and an agent, such as a chemotherapeutic agent (col. 2, lines 24-26 and 34-37). Widder explains that its microspheres can be localized at the desired site using an applied magnetic field (*see* col. 2, lines 41-46). Widder emphasizes that it is of “critical importance that the microspheres have a degree of magnetic responsiveness” that permits them to be guided to and localized in the desired site (*Id.*). Widder explains that this result is best achieved by concentrating the magnetic particles in the peripheral portions of the microspheres, instead of uniformly distributing the magnetic

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particles throughout the microspheres (col. 3, lines 36-40). Widder does not disclose the claimed elastic seeds or strands which include setae or anchoring structures.

The combined references

The combination of Zamora with Widder does not make claim 15 obvious. In particular, neither Zamora nor Widder disclose the claimed elastic seeds or strands which include setae or anchoring structures. Zamora teaches that the density of the device is the means by which migration of the device is prevented. In contrast, Widder teaches that the inclusion of magnetic particles on the surface of the microspheres is necessary to guide and localize the microspheres in the desired location using an external magnet. In contrast, claim 15, which depends for claim 1 (and therefore includes the limitations of claim 1), specifies that the elastic seeds or strands which include setae or anchoring structures. These materials are included in the seeds or strands to prevent migration following implantation. Therefore claim 15 is not obvious in view of the combination of Zamora with Widder.

Double Patenting Rejection

Claims 1-14, 16-20, 22-24, and 27-35 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 10, 12, 15, 30, 32, 35, and 26 of U.S. Patent No. 6,746,661 to Kaplan (“Kaplan ‘661”). Claims 25 and 26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,514,193 to Kaplan (“Kaplan ‘193”).

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Applicant will file a terminal disclaimer in response to these rejections once the claims are otherwise determined to be allowable.

Additional Amendments to the claims

Claim 16 was amended to clarify that the strand contains a plurality of seeds. Support for this amendment can be found in the specification at least at page 6, lines 4-5. Claim 20 was amended to correspond with the language used in amended claim 1. Claim 28 was canceled in view of the amendment to claim 1. Claims 29 and 35 were amended to depend from claim 1, in view of the cancellation of claim 28. Claim 34 was amended to specify that the strand further comprises spacers. Support for this amendment can be found in the specification at least at page 6, lines 4-5.

Allowance of claims 1-20, 22-27, and 29-35, as amended, is respectfully solicited.

Respectfully submitted,

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